details are being collected and the same will be laid on the Table of the House.

DCGI's control on state drug controllers

2361. SHRI UDAY PRATAP SINGH: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that State Drug Controllers have approved number of fixed dose combinations which have not been approved by the DCGI;

(b) whether it is also a fact that DCGI is not able to exercise control on the State Drug Controllers; and

(c) the details of all the fixed dose combinations which have been approved by the DCGI during the last one year?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) to (c) Some instances have come to the notice regarding approval of fixed dose combinations by State Drug Licensing Authorities which otherwise need approval from the office of DCG(I).

All State Drug Licensing Authorities have been directed by the office of DCG(I) not to approve such fixed dose combinations which fall within the definition of "New Drug" as per Drugs and Cosmetics Rules.

Health Ministry had also written to all State Government to appraise State Drug Licensing Authorities in this Matter.

Whenever instances of such approval of fixed dose combinations come to the notice of office of DCG(I), the concerned State Drug Licensing Authorities have been directed to withdraw permission given by them.

The list of fixed dose combinations approved by DCG(I) during last one year *i.e.,* from June, 2005 to June, 2006 is enclosed at Statement.

Statement

List of DCs approved from June 2005 to June 2006

Name of fixed dose combination	Dose	Dosage from
Gatiflozacin + Ornidazole	200+500mg	Tablets
Lamivudine + Abacavir	300mg + 600mg	Tablets
Lamivudine + Stavudine + Efavirenz	150mg + 40mg + 600mg	Combikit
Lamivudine + Zidovudine + Efavirenz	150mg + 300mg + 600mg	Combikit
Aceclofenac + Linseed Oil + Methyl Salicylate + Menthol + Capsaicin	1.5%+ 3%+ 10%+ 5% + 0.025%	Gel
Losartan + Atenolol	50mg + 50mg	FC Tablets
Nitrazoxanide + Ofloxacin	50mg + 200mg	Tablets
Papain + Urea	>521700 Units + 100 mg	Ointment
Amoldipine + Bisoprolol	5 mg + 2.5/5mg	FC Tablets
Ceftriaxone + Tazobactam	0.5/1lg + 62.5/125mg	Inj.
Levodopa + Carbidopa + Entacapone	50/100/150mg + 12.5/25/ 37.5mg + 200mg	FC Tablets
Atorvaststin + Nicotinic Acid	10mg + 375/500mg (ER)	Tablets
Ambroxol + Levocetrizine	75mg SR + 5mg	Capsules

Name of fixed dose combination	Dose	Dosage from
Methylcobalamin + Gabapentin	500mcg + 300mg	FC Tablets
Stavudine + Lamivudine	6/12mg + 30/60mg	Dispersible Tablets
Glimepiride + Pioglitazone + Metformin	1/2mg + 15mg + 500mg ER	FC Tablets
Calcipotriol + Betamethasone	50mcg + 0.5mg	Ointment
Methylcobalamin + Pyridoxine + Folic Acid	1500mcg(ER) + 20mg(IR) + 5mg (IR)	Tablets
Nimesulide + Methyl Salicylate	1% +5%	Aerosol
Feracrylum + Metronidazole	1% + 1%	Gel
Enalapril + HCTZ	2.5/5mg + 12.5mg	Tablets
Tazarotene + Memetasone	0.05% 0.1%+ 0.1%	Lotion
Ambroxole + Desloratadine	75mg SR pellets + 5mg	Capsules
s(-) Metoprol + HCTZ	25/50mg(ER) + 12.5mg(IR)	Tablets
Stavudine + Lamivudine + Nevirapine	10mg + 40mg + 70mg	Dispersible Tablets
Domperiodone + Activated Dimethicone	10mg + 125mg	Chewable Tablets
Moxifloxacin + Dexamethsaone	o.5mg W/v + 0.1% w/v	Eye Drops
Brimonidine + Timolol	0.5/0.2% + 0.5%	Eye Drops

Olmesartan + HCTZ	20/40mg + 12.5mg	Tablets
Ketorolac Tromethamine + Ofloxacin	Each ml contains: 5mg + 3mg	Ophthalmic Solution
Hyoscine-N-Butyl Bromide + Paracetamol	10mg + 500mg	FC Tablets
Losartan + Amlodipine	50+5mg	FC Tablets
Ceftriaxohe + Sulbactam	0.5/1g + 250/500mg	Injection
Tamsulosin + Dutasteride	0.4mg MR pellets + 0.5mg	Combinpack Capsules
Nebivolol + Valsartan	5mg Tab + 80mg Tab	Tablets
Alendronic acid + Cholecalciferol	70mg + 2800 IU	FC Tablets
Asprin + Clopidogrel	150mg + 300mg	Tablets
S(-) Amlodepine + HCTZ	2.5mg + 12.5mg	Tablets
Tenofovir Disoproxil Furnarate + Emtricitabine	300 + 200mg	FC Tablets
Diclofenac Sodium + Misoprostol	50/75mg (EC tab) + 200mcg	Tablets
Pantoprazole + Itopride	40mg EC granules + 150mg SR Pellets	Capsules
Amlodepine + Metoprolol	5mg + 50mg	Capsules
Nebivolol + Amlodipine	5mg + 10mg	FC Tablets
Gatifloxacin + Prednisolone	Each ml contains: 3mg + 10mg	Eye Drops